



**DEPARTMENT OF JUSTICE**

**Drug Enforcement Administration**

**[Docket No. DEA-420F]**

**Final Adjusted Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2016**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice (DOJ).

**ACTION:** Final order.

**SUMMARY:** This final order establishes the final adjusted 2016 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA) and the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine.

**DATES:** This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**FOR FURTHER INFORMATION CONTACT:** Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152, Telephone: (202)598-6812.

**SUPPLEMENTARY INFORMATION:**

**Legal Authority**

Section 306 of the Controlled Substances Act (CSA) (21 U.S.C. 826), requires the Attorney General to establish aggregate production quotas for each basic class of

controlled substances listed in schedules I and II and for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. The Attorney General has delegated this function to the Administrator of the DEA pursuant to 28 CFR 0.100.

## **Background**

The DEA published the 2016 established aggregate production quotas for controlled substances in schedules I and II and for the assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine in the *Federal Register* on October 6, 2015. 80 FR 60400. This notice stated that the Administrator would adjust, as needed, the established aggregate production quotas in 2016 in accordance with 21 CFR 1303.13 and 21 CFR 1315.13. The 2016 proposed adjusted aggregate production quotas for controlled substances in schedules I and II, and assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine were subsequently published in the *Federal Register* on July 22, 2016, (81 FR 47829) in consideration of the outlined criteria. All interested persons were invited to comment on or object to the proposed adjusted aggregate production quotas and assessment of annual needs on or before August 22, 2016.

## **Comments Received**

Four DEA-registered entities submitted timely comments regarding a total of six schedule I and II controlled substances. Comments received proposed that the aggregate production quotas for amphetamine (for sale), etorphine hydrochloride, methadone, methadone intermediate, nabilone, and phencyclidine were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks. The

DEA received one comment from a non-DEA registered entity requesting the reduction of oxycodone (for sale) to pre-2013 levels. The DEA received one comment from a DEA registrant regarding the proposed removal of the additional 25% of the estimated medical, scientific, and research needs of the United States for the calendar year 2017 published in the *Federal Register* on July 22, 2016 (81 FR 47821).

The DEA received one comment from a DEA-registered entity and two comments from non-DEA registered entities for the proposed adjustments to the 2016 assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Comments received proposed that the annual assessment of needs for ephedrine (for sale) and pseudoephedrine (for sale) were insufficient to provide for the estimated medical, scientific, research, and industrial needs of the United States, for export requirements, and for the establishment and maintenance of reserve stocks.

#### **Analysis for Final Adjusted 2016 Aggregate Production Quotas and Assessment of Annual Needs**

In determining the final adjusted 2016 aggregate production quotas and assessment of annual needs, the DEA has taken into consideration the above comments along with the factors set forth in 21 CFR 1303.13 and 21 CFR 1315.13 in accordance with 21 U.S.C. 826(a), and other relevant factors including the 2015 year-end inventories, initial 2016 manufacturing and import quotas, 2016 export requirements, actual and projected 2016 sales, research and product development requirements, and additional applications received. Based on all of the above, the Administrator has determined that the proposed adjusted 2016 aggregate production quotas and assessment of annual needs for amphetamine (for sale), etorphine hydrochloride, dextropropoxyphene, levorphanol,

nabilone, noroxymorphone (for sale), phencyclidine, and secobarbital required additional consideration, and hereby further adjusts the 2016 aggregate production quotas and assessment of annual needs for these substances. This final order reflects those adjustments.

Regarding ephedrine (for sale), methadone, methadone intermediate, oxycodone (for sale), and pseudoephedrine (for sale) the Administrator hereby determines that the proposed adjusted 2016 aggregate production quotas and assessment of annual needs for these substances and list I chemicals as published on July 22, 2016, (81 FR 47829) are sufficient to meet the current 2016 estimated medical, scientific, research, and industrial needs of the United States and to provide for adequate reserve stock. This final order establishes these aggregate production quotas at the same amounts as proposed.

As described in the previously published notice establishing the 2016 aggregate production quotas and assessment of annual needs, the DEA has specifically considered that inventory allowances granted to individual manufacturers may not always result in the availability of sufficient quantities to maintain an adequate reserve stock pursuant to 21 U.S.C. 826(a), as intended. 21 CFR 1303.24. This would be concerning if a natural disaster or other unforeseen event resulted in substantial disruption to the amount of controlled substances available to provide for legitimate public need. As such, the DEA included in all final schedule II aggregate production quotas, and certain schedule I aggregate production quotas, an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. The resulting final aggregate production quotas will reflect these included amounts. This action will not affect the ability of manufacturers to

maintain inventory allowances as specified by regulation. The DEA expects that maintaining this reserve in certain established aggregate production quotas will mitigate adverse public effects if an unforeseen event results in the substantial disruption to the amount of controlled substances available to provide for legitimate public need, as determined by the DEA. The DEA does not anticipate utilizing the reserve in the absence of these circumstances.

Pursuant to the above, the Administrator hereby finalizes the 2016 aggregate production quotas for the following schedule I and II controlled substances and the 2016 assessment of annual needs for the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, expressed in grams of anhydrous acid or base, as follows:

<b>Basic Class</b>	<b>Revised 2016 Quotas</b>
	<b>(g)</b>
<b>Temporarily Scheduled Substances</b>	
beta-Hydroxythiofentanyl	30
Butyryl fentanyl	30
<b>Schedule I</b>	
[1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	15
1-(1-Phenylcyclohexyl)pyrrolidine	10
1-(5-Fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	45
1-(5-Fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	45
1-[1-(2-Thienyl)cyclohexyl]piperidine	15
1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	45
1-Benzylpiperazine	25
1-Butyl-3-(1-naphthoyl)indole (JWH-073)	45
1-Cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8)	45
1-Hexyl-3-(1-naphthoyl)indole (JWH-019)	45

1-Methyl-4-phenyl-4-propionoxypiperidine	2
1-Pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	45
1-Pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	45
1-Pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	45
1-Pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	45
1-Pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	45
1-Pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19, RCS-4)	45
1-Pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	45
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	30
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	30
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	30
2-(2,5-Dimethoxy-4-n-propylphenyl)ethanamine (2C-P)	30
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	30
2-(4-Bromo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25B-NBOMe; 2C-B-NBOMe; 25B; Cimbi-36)	25
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	30
2-(4-Chloro-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25C-NBOMe; 2C-C-NBOMe; 25C; Cimbi-82)	25
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	30
2-(4-Iodo-2,5-dimethoxyphenyl)-N-(2-methoxybenzyl)ethanamine (25I-NBOMe; 2C-I-NBOMe; 25I; Cimbi-5)	15
2,5-Dimethoxy-4-ethylamphetamine (DOET)	25
2,5-Dimethoxy-4-n-propylthiophenethylamine	25
2,5-Dimethoxyamphetamine	25
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	30
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	30
3,4,5-Trimethoxyamphetamine	25
3,4-Methylenedioxyamphetamine (MDA)	55
3,4-Methylenedioxymethamphetamine (MDMA)	50
3,4-Methylenedioxy-N-ethylamphetamine (MDEA)	40
3,4-Methylenedioxy-N-methylcathinone (methyldone)	50
3,4-Methylenedioxypropylamphetamine (MDPV)	35
3-FMC; 3-Fluoro-N-methylcathinone	25
3-Methylfentanyl	2
3-Methylthiofentanyl	2
4-Bromo-2,5-dimethoxyamphetamine (DOB)	25
4-Bromo-2,5-dimethoxyphenethylamine (2-CB)	25

4-FMC; Flephedrone	25
4-Methoxyamphetamine	150
4-Methyl-2,5-dimethoxyamphetamine (DOM)	25
4-Methylaminorex	25
4-MEC; 4-Methyl-N-ethylcathinone	25
4-Methyl-N-methylcathinone (mephedrone)	45
4-Methyl- $\alpha$ -pyrrolidinopropiophenone (4-MePPP)	25
5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol	68
5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog)	53
5-Fluoro-UR144, XLR11	25
5-Methoxy-3,4-methylenedioxyamphetamine	25
5-Methoxy-N,N-diisopropyltryptamine	25
5-Methoxy-N,N-dimethyltryptamine	25
AB-PINACA	15
Acetyl-alpha-methylfentanyl	2
Acetyldihydrocodeine	2
Acetylmethadol	2
AH-7921	30
Allylprodine	2
alpha-Ethyltryptamine	25
alpha-Methylfentanyl	2
alpha-Methylthiofentanyl	2
alpha-Methyltryptamine (AMT)	25
alpha-Pyrrolidinobutiophenone ( $\alpha$ -PBP)	25
alpha-Pyrrolidinopentiophenone ( $\alpha$ -PVP)	25
Alphacetylmethadol	2
Alphameprodine	2
Alphamethadol	2
Aminorex	25
APINCA, AKB48	25
Benzylmorphine	2
beta-Hydroxy-3-methylfentanyl	2
beta-Hydroxyfentanyl	2
Betacetylmethadol	2
Betameprodine	2

Betamethadol	4
Betaprodine	2
Bufotenine	3
Butylone	25
Cathinone	30
Codeine methylbromide	5
Codeine-N-oxide	305
Desomorphine	25
Diethyltryptamine	25
Difenoxin	11,000
Dihydromorphine	2,000,000
Dimethyltryptamine	35
Dipipanone	5
Fenethylamine	5
gamma-Hydroxybutyric acid	70,250,000
Heroin	50
Hydromorphanol	2
Hydroxypethidine	2
Ibogaine	5
Lysergic acid diethylamide (LSD)	40
Marihuana	658,000
Mescaline	25
Methaqualone	10
Methcathinone	25
Methyldesorphine	5
Methyldihydromorphine	2
Morphine methylbromide	5
Morphine methylsulfonate	5
Morphine-N-oxide	350
N,N-Dimethylamphetamine	25
N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (ADB-PINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA)	50
N-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide (AB-CHMINACA)	15
N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl)	100



N-Ethyl-1-phenylcyclohexylamine	5
N-Ethylamphetamine	24
N-Hydroxy-3,4-methylenedioxyamphetamine	24
Naphyrone	25
Noracymethadol	2
Norlevorphanol	52
Normethadone	2
Normorphine	40
Para-fluorofentanyl	5
Parahexyl	5
Pentedrone	25
Pentylone	25
Phenomorphane	2
Pholcodine	5
Psilocybin	30
Psilocyn	50
Quinolin-8-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22)	25
Quinolin-8-yl 1-pentyl-1H-indole-3-carboxylate (PB-22; QUPIC)	25
Tetrahydrocannabinols	511,250
Thiofentanyl	2
Tilidine	25
Trimeperidine	2
UR-144	25
<b>Schedule II</b>	
1-Phenylcyclohexylamine	5
1-Piperidinocyclohexanecarbonitrile	5
4-Anilino-N-phenethyl-4-piperidine (ANPP)	2,250,000
Alfentanil	17,750
Alphaprodine	3
Amobarbital	25,125
Amphetamine (for conversion)	15,000,000
Amphetamine (for sale)	50,000,000
Carfentanil	19
Cocaine	200,000
Codeine (for conversion)	50,000,000

Codeine (for sale)	63,900,000
Dextropropoxyphene	55
Dihydrocodeine	226,375
Dihydroetorphine	3
Diphenoxylate (for conversion)	18,750
Diphenoxylate (for sale)	1,337,500
Ecgonine	125,000
Ethylmorphine	5
Etorphine hydrochloride	40
Fentanyl	2,300,000
Glutethimide	3
Hydrocodone (for conversion)	177,500
Hydrocodone (for sale)	86,000,000
Hydromorphone	7,000,000
Isomethadone	5
Levo-alphaacetylmethadol (LAAM)	4
Levomethorphan	33
Levorphanol	9,525
Lisdexamfetamine	23,750,000
Meperidine	4,632,500
Meperidine Intermediate-A	6
Meperidine Intermediate-B	11
Meperidine Intermediate-C	6
Metazocine	19
Methadone (for sale)	31,875,000
Methadone Intermediate	34,375,000
Methamphetamine	2,061,375
[1,250,000 grams of levo-desoxyephedrine for use in a non-controlled, non-prescription product; 750,000 grams for methamphetamine mostly for conversion to a schedule III product; and 61,375 grams for methamphetamine (for sale)]	
Methylphenidate	84,375,000
Morphine (for conversion)	91,250,000
Morphine (for sale)	62,500,000
Nabilone	18,875
Noroxymorphone (for conversion)	17,500,000
Noroxymorphone (for sale)	875,000
Opium (powder)	112,500

Opium (tincture)	375,000
Oripavine	30,000,000
Oxycodone (for conversion)	5,000,000
Oxycodone (for sale)	139,150,000
Oxymorphone (for conversion)	25,000,000
Oxymorphone (for sale)	6,250,000
Pentobarbital	38,125,000
Phenazocine	6
Phencyclidine	60
Phenmetrazine	3
Phenylacetone	50
Racemethorphan	5
Racemorphan	3
Remifentanil	3,750
Secobarbital	243,380
Sufentanil	6,255
Tapentadol	25,500,000
Thebaine	125,000,000
<b>List I Chemicals</b>	
Ephedrine (for conversion)	50,000
Ephedrine (for sale)	4,000,000
Phenylpropanolamine (for conversion)	15,000,000
Phenylpropanolamine (for sale)	8,500,000
Pseudoephedrine (for conversion)	40
Pseudoephedrine (for sale)	200,000,000

Aggregate production quotas for all other schedule I and II controlled substances included in 21 CFR 1308.11 and 1308.12 remain at zero.

Dated: October 19, 2016

Chuck Rosenberg,  
*Acting Administrator.*

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